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**UNITED STATES DISTRICT COURT**
**DISTRICT OF NEW JERSEY**

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| IN RE BIOGEN '755 PATENT LITIGATION | Civil Action No. 10-cv-02734 (CCC) (JBC) (consolidated) |

# BAYER'S MEMORANDUM OF LAW IN OPPOSITION TO BIOGEN'S MOTION TO STRIKE THE EXPERT REPORT OF GORDON P. MOORE

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Biogen's motion is a desperate and transparent attempt to strike an anticipation argument that ends the case against Bayer. Bayer has alleged since the initial exchange of invalidity contentions in 2011 that the Weissmann patent anticipates the only claim asserted against Bayer. With its opening expert reports, Bayer provided experimental proof that this contention was correct—that the polypeptide of Weissmann falls within the scope of Biogen's claim. Having no factual response to this evidence, Biogen understandably wants it to disappear. The law does not permit that result. The fact that the evidence was developed by an expert and thus was disclosed in his expert report does not make it untimely, and the fact that it is fatal to Biogen's case does not make it prejudicial.

Biogen's motion rests on several faulty premises. First, it argues that Bayer "violated Local Patent Rules 3.3 and 3.4" because its contentions were insufficiently detailed. This allegation would be meritless even had Biogen not expressly agreed—as it remarkably neglects to mention—that it would "*NOT ASSERT THAT* Bayer's invalidity contentions *DO NOT* comply with the local rules."

Second, Biogen argues that because Bayer's expert performed testing at the request of outside counsel during the fact discovery period, Bayer was obligated to disclose the expert's work during fact discovery rather than in his expert report. This argument is a breathtaking feat of chutzpah: Biogen's own expert reports relied on analogous experimental testing to support its infringement contentions, yet Biogen

failed to produce the underlying test documents until *after* the expert reports was served. In any event, Biogen cites no law to support the notion that either side's expert materials needed to be served before expert discovery; such a notion would fly in the face of both the Court's Scheduling Order and the law of work product. Far from demonstrating the bad faith required to strike a defense, Bayer's actions were entirely appropriate and mirrored Biogen's own justifiable practice.

Third, Biogen attempts to manufacture a discovery violation on the basis of Bayer's response to an interrogatory relating to invalidity defenses that—unlike anticipation by Weissmann—were not the subject of the invalidity contentions. Even if the testing fell within the scope of the interrogatory response, which it did not, the interrogatory could not obligate Bayer to produce expert discovery before expert discovery. Biogen's suggestion that it relied to its prejudice on a representation that Bayer was not withholding responsive documents is baseless.

Finally, Biogen was not unfairly prejudiced. Bayer produced everything Biogen needed to respond to Bayer's evidence. With the materials Bayer produced in hand, the experiment Bayer performed (which Biogen could have replicated) takes about a week, not the months or years Biogen has suggested. At the time of its choosing, Biogen responded to Bayer's evidence and chose not to include testing of its own. Biogen cannot claim prejudice on the basis of its own strategic decision.

For all these reasons, Biogen's motion should be denied.

## I. BAYER'S DISCLOSURES WERE SUFFICIENT AND TIMELY

Biogen's motion recites a misleading version of the facts, and then addresses whether Biogen was prejudiced and how Bayer should be sanctioned. Biogen ignores the trenchant question of whether Bayer failed to comply with its discovery obligations. In fact, there is no discovery violation to sanction.

### A. Bayer's Invalidity Contentions Were Sufficient—As Biogen Agreed

1. The foundational premise of Biogen's motion is that Biogen would have acted differently if Bayer had "disclosed its contentions years ago as it should have done." Mot. at 10. But Biogen cannot wish away a key fact that is fatal to its motion: Bayer *did* disclose its contentions years ago.

From Bayer's first invalidity contentions in 2011, Bayer has consistently contended that Weissmann anticipates claim 1 of Biogen's '755 patent. Ex. A at 14; Ex. B at 14; Ex. C at 14-15. Necessarily, under the "black letter law" that Biogen itself invokes, Bayer thereby contended that Weissmann "expressly or inherently discloses every single limitation of the patent claim at issue." Mot. at 5; *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016). That includes the "capable of hybridizing" and "washing conditions" limitations on which Biogen has now focused. Mot. at 5-6, 10-13. Indeed, Bayer's claim chart alleging anticipation by Weissmann cited the specific column and line numbers where it discloses a recombinant polypeptide, and the DNA encoding it, on which Bayer

relies to meet the capable-of-hybridization requirement of claim 1. Ex. D at 96.

2. Unable to dispute that Bayer's Weissmann anticipation defense has always been in its contentions, Biogen alleges that the claim charts provided with the contentions were insufficiently specific. Mot. at 5-6. This purported failure, Biogen argues, "violated Local Patent Rules 3.3 and 3.4." Mot. at 2.

Biogen declined to advise the Court that the claim charts at issue arose from a lengthy negotiation between Bayer and Biogen regarding the level of disclosure required by the Local Rules and the sufficiency of Bayer's disclosure. Ex. E at 2. At the conclusion of this negotiation, Bayer agreed to supplement its contentions in an agreed-upon manner, and Biogen expressly agreed that it would "*NOT ASSERT THAT* Bayer's invalidity contentions *DO NOT* comply with the local rules." *Id*. at 3 (emphasis in original). Bayer honored its agreement by serving Second Amended Invalidity Contentions with agreed-upon additional information. Ex. C; Ex. D.

Biogen did not then complain that the anticipation chart for Weissmann was insufficiently detailed. The chart provided Bayer's contentions that Weissmann anticipates, including the particular disclosures that meet the hybridization limitations of claim 1. Biogen knew that the law requires that Weissmann meet those limitations to anticipate claim 1. If Biogen had any question about *how* or *why* Bayer believed Weissmann mapped onto claim 1, Biogen could have either requested more detail (just as it did for other of Bayer's contentions, Ex. E at 2) or served subsequent

discovery regarding Bayer's anticipation defense (just as it did for other defenses, *see* Ex. F at 6-7). Biogen did neither. Instead, Biogen agreed that Bayer's anticipation disclosures were sufficient and represented clearly (in capital, italicized letters) that it would "*NOT ASSERT THAT* Bayer's invalidity contentions *DO NOT* comply with the local rules." Ex. E at 3. Biogen may not now abrogate this agreement that defeats the premise of its motion (that Bayer's contentions do not comply with the local rules, Mot. at 1-2). Giving Biogen's attorneys the benefit of the doubt that they did not intend to mislead the Court but somehow forgot their own agreement, Biogen should end this embarrassment and withdraw its motion.

3. In any event, as Biogen recognized, Bayer's contentions fully comply with the Rules. Bayer disclosed the contention that Weissmann anticipates and identified particular portions of Weissmann that meet the hybridization limitation. Ex. C at 14-15; Ex. D at 96. That is all the Rules require; Bayer pointed to "where specifically in each alleged item of prior art each limitation of each asserted claim is found." L. Pat. R. 3.3(c). What Bayer's later-disclosed expert evidence provides is *proof* that Weissmann in fact meets the hybridization limitation. That is, Weissmann anticipates because polypeptides it discloses—to which Bayer pointed in its contentions—satisfy the requirements of claim 1, and Dr. Moore's testing shows that they do. But this evidence (which did not exist when the contentions were served) goes beyond the Rules, as it is not found in Weissmann, which does not refer to the

hybridization test that Biogen later recited in claim 1 of the '755 patent.[1]

Moreover, the Rules recognize that expert discovery will follow fact discovery, stating that the Court can set a schedule providing that "disclosure of expert materials related to issues other than claim construction will not be required until claim construction issues have been decided." L. Pat. R. 2.4. The Court did just that in this case, ordering that opening expert reports be served within sixty days "after the issuance of the Court's Markman decision or the close of fact discovery, whichever is later . . . ." ECF No. 37 at 4. Bayer's disclosure was fully compliant with the Local Patent Rules and the Court's Scheduling Order.

### B. Bayer Had No Obligation To Disclose Dr. Moore's Testing Before Expert Discovery

Biogen's second line of attack is to argue that Dr. Moore's test results should have been produced during fact discovery. Mot. at 6-8. Biogen's say-so, however, does not give rise to any such obligation. Dr. Moore is an expert consultant retained by Bayer's outside trial counsel to perform testing and render opinions. His testing is a paradigmatic example of "facts or data considered by [an expert] witness" under Fed. R. Civ. P. 26(a)(2)(B), and Bayer was obligated to disclose it with an expert

[1] Biogen's reliance on the current version of L. Pat. R. 3.4(c) (Mot. at 5) is misplaced; all parties have followed the pre-2011 version of the Rules, which did not require disclosure of any documents beyond the anticipatory references. Likewise, Biogen never served responses to the contentions as the Rules now require.

report during expert discovery. It did so, on the required date for opening reports.

Biogen cites only one case relating to untimely expert disclosures. *Reckitt Benckiser Inc. v. Tris Pharma, Inc.*, 2011 WL 6722707 (D.N.J. Dec. 21, 2011). *Reckitt* demonstrates the propriety of Bayer's disclosures. It addressed a disclosure of expert evidence *after* the time provided in the schedule for making such disclosures, in response to a motion for summary judgment. *Reckitt* specifically noted that this disclosure "contained substantial new data and information that went well beyond the scope of [the expert's] opening report." *Id*. at *3. This case, in contrast, involves a disclosure *in Bayer's opening expert reports*—exactly when it was supposed to be disclosed. Biogen cites no authority suggesting that experimental work performed by a retained expert witness must be disclosed before opening expert reports, much less a case that imposes a sanction for failure to do so.

The absence of such authority is no surprise. Scientific testing conducted for the purpose of litigation is protected work product until a party chooses to disclose and rely on it. *Reckitt Benckiser LLC v. Amneal Pharms., LLC*, 2012 WL 2871061, at *6 (D.N.J. July 12, 2012) (denying motion to compel production of testing protocol during fact discovery, because such materials are protected work product); *Sicurelli v. Jeneric/Pentron Inc.*, 2006 WL 1329709, at *2 (E.D.N.Y. May 16, 2006) (documents relating to litigation testing not considered by testifying expert are protected work product). Until Bayer served an expert report disclosing Dr. Moore's

hybridization data, they were protected as work product, and Biogen was not entitled to them. And once Bayer designated Dr. Moore a potential testifying expert, Bayer timely disclosed his opinions and associated notebooks and materials.[2]

Biogen's own conduct demonstrates its understanding of the well-accepted rule that an expert's testing materials need not be disclosed during fact discovery. To prove infringement, Biogen must demonstrate (*inter alia*) that Bayer's accused product, Betaseron®, meets the very same hybridization limitations that Dr. Moore's testing addresses with respect to Weissmann. Unsurprisingly, Biogen retained its own expert to perform experimental testing to support its infringement case, and that expert, Dr. Couceyro, conducted experiments in 2013 and 2014. Ex. I; Ex. J. Biogen first disclosed this testing in Dr. Couceyro's initial expert report in 2016—not when it was conducted. In fact, Dr. Couceyro did not produce the underlying documents until more than a month after serving his report, despite numerous requests from Bayer. Exs. K-M. Biogen's actions before it became aware of Dr. Moore's

[2] One testing document created by Dr. Moore was shown to a Biogen witness during a deposition, *see* Ex. G at 103-05; Ex. H, at which point that document no longer was protected work product. There was no broader subject-matter waiver of work product protection, because no protected information was "partially disclosed to a decision maker in an effort to influence a decision." *Mitre Sports Int'l Ltd. v. Home Box Office, Inc.*, 304 F.R.D. 369, 373 (S.D.N.Y. 2015); Fed. R. Evid. 502(a) cmt. (subject-matter waiver of work product applies only in "unusual situations . . . to prevent a selective and misleading presentation of evidence"). Bayer produced all relevant materials before any were presented to the Court or a jury. In any event, other than passing questions in the deposition—which Bayer answered—Biogen did not seek any further information about the document or related materials.

irrefutable evidence of anticipation are far more reliable than its present, legally foreclosed argument that Bayer was obligated to disclose Dr. Moore's testing during fact discovery. Biogen acted properly in waiting to disclose Dr. Couceyro's testing until expert discovery, and Bayer should not be sanctioned for doing the same.

### C. Bayer's Interrogatory Responses Did Not Create an Obligation To Disclose Dr. Moore's Testing

Finally, Biogen's motion relies on Bayer's response to an interrogatory asking for "all facts" supporting certain of Bayer's invalidity theories. Mot. at 7. Biogen argues that Bayer did not include Dr. Moore's testing in its response and therefore could not disclose it in expert discovery. But Biogen's discovery requests cannot impose on Bayer an obligation to disclose expert materials before expert discovery. More importantly, the response on which Biogen relies begins with the following text, which alone defeats Biogen's argument (and which, remarkably, it ignores):

> Bayer objects to this interrogatory on the ground that and to the extent that it seeks information that is properly the subject of expert discovery, which Bayer will disclose at the appropriate time consistent with the scheduling orders of the Court.

Ex. O at 3. The response was clear: it did not include any "information that is properly the subject of expert discovery," and Bayer would disclose that information "at the appropriate time consistent with the scheduling orders of the Court." The notion that it undertook an obligation to furnish information protected by work product during fact discovery is belied by the response that Biogen

brazenly ignores. It is also belied, once again, by Biogen's own conduct; if Dr. Moore's testing were responsive to Interrogatory 2, then Dr. Couceyro's testing—which Biogen did not produce until expert discovery—was responsive to Bayer's requests for production. *See* Ex. U at 54. In fact, both parties treated their own experts' testing as the proper subject of expert discovery, not fact discovery.

The reality, moreover, is that Biogen's interrogatory never sought discovery about Bayer's anticipation contention. The interrogatory was served in 2010 (before the invalidity contentions), and Bayer quite reasonably interpreted it to relate to invalidity defenses *other than* those that Bayer would ultimately list in its contentions; it sought, "[t]o the extent not disclosed in Defendants' Invalidity Contentions," "all facts" supporting any of Bayer's invalidity defenses. Ex. N at 6. Bayer then provided information related to defenses, such as inventorship and double patenting, that were not the subject of the invalidity contentions. Ex. O. Its response did not address its anticipation arguments. Before this motion, Biogen never objected to this interpretation of its interrogatory.

Biogen makes much of Bayer's representation that it was not "withholding or refusing to identify documents or testimony that it currently believes are responsive to Biogen's interrogatories." Mot. at 7. This representation was accurate. First, prior to this motion, no one ever suggested that Interrogatory 2 obligated Bayer to provide additional information about its anticipation defense, about which Bayer had

already provided detailed contentions. The email exchange on which Biogen relies arose from a meet-and-confer about other interrogatories and issues. Exs. P-R.

Second, Bayer believed (correctly) that disclosure of test data generated by retained experts was premature until expert discovery. In the very same email Biogen now cites, Bayer emphasized:

> our expert reports are not due for some time, and our experts have not completed their analysis. Accordingly, Bayer, or its experts, may rely on additional documents or testimony that it did not disclose in response to Biogen's interrogatories . . . . If that happens, our expert reports will disclose our experts' intention to rely on those other documents or testimony, or we will supplement our interrogatories, as appropriate.

Ex. R at 1. Bayer noted that, because its expert reports on invalidity were due before Biogen's, Biogen would have "ample opportunity to respond to anything we disclose." *Id*. Biogen "recognize[d Bayer's] position that Bayer's experts may identify other documents or testimony as being responsive to these interrogatories and may rely on those documents and testimony to support opinions about the topics called for by those interrogatories," *id*. at 2, thereby agreeing to the procedure that Bayer followed. The notion that Bayer withheld information it should have provided, or that this unrelated discovery exchange somehow affects the analysis of when Dr. Moore's data should have been disclosed, is baseless.

## II. THERE IS NO BASIS FOR EXCLUDING ANY EVIDENCE

Exclusion of case-dispositive evidence is an "extreme sanction." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 297 (3d Cir. 2012); *Meyers v. Pennypack Woods*

*Home Ownership Ass'n*, 559 F.2d 894, 905 (3d Cir. 1977). "Courts in the Third Circuit" are reluctant to exclude evidence because they "favor resolution of disputes on their merits, particularly with respect to patent validity issues, which raise public interest concerns extending beyond the immediate dispute between the parties." *EMC Corp. v. Pure Storage, Inc.*, 154 F. Supp. 3d 81, 93 (D. Del. 2016). Even were the Court somehow to find a discovery violation, the *Pennypack* factors all indicate that Bayer's critical evidence regarding invalidity should be considered on the merits, not excluded. And not surprisingly, a host of cases applying the *Pennypack* factors have reached the conclusion that exclusion is inappropriate.[3]

### A. Dr. Moore's Testimony Is Critical Invalidity Evidence

The Third Circuit has recognized that "[t]he importance of the evidence is often the most significant factor" in the *Pennypack* analysis. *ZF Meritor*, 696 F.3d at 298. Dr. Moore's testing is case-dispositive; it demonstrates that a polypeptide disclosed by Weissmann is encoded by DNA that meets the hybridization limitation of claim 1, which is therefore invalid as anticipated. Were it otherwise, Biogen

[3] *See, e.g.*, *ZF Meritor*, 696 F.3d 254; *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791-92 (3d Cir. 1994); *Abbott Labs. v. Lupin Ltd.*, 2012 WL 1994477 (D.N.J. June 4, 2012); *Ford Motor Co. v. Edgewood Props., Inc.*, 2011 WL 5828661 (D.N.J. Nov. 18, 2011); *Rowe v. E.I. du Pont de Nemours & Co.*, 2010 WL 703210 (D.N.J. Feb. 24, 2010); *Ortho-McNeil Pharm. v. Barr Labs.*, 2006 WL 1805897 (D.N.J. June 29, 2006); *Love v. Rancocas Hosp.*, 2005 WL 6011252 (D.N.J. Mar. 31, 2005); *Gen. Refractories Co. v. First State Ins. Co.*, 2014 WL 5149072 (E.D. Pa. Oct. 10, 2014); *Novartis Pharm. Corp. v. Actavis, Inc.*, 2013 WL 7045056 (D. Del. Dec. 23, 2013).

would not desperately seek to exclude it, in disregard of its own promises and controlling authority. This is precisely the type of exclusion *Pennypack* disfavors, particularly in a patent case implicating "public interest concerns" in adjudicating the validity of a government monopoly grant. *EMC*, 154 F. Supp. 3d at 93.

**B. Biogen Was Not Prejudiced**

Biogen cannot show prejudice for at least three reasons. First, contrary to its arguments (Mot. at 13-14), Biogen has not been denied the opportunity to take discovery or to perform its own testing. Bayer produced all of the information supporting the opinions in Dr. Moore's report at the outset of expert discovery. It also made available the original lab notebooks and x-ray films (which provided a detailed, contemporaneous record), and the reagent samples Biogen could use to replicate Dr. Moore's experiments (which Biogen returned to Bayer without testing them). Dr. Moore will be deposed—his deposition is already scheduled—and he personally supervised the experiments at issue. And Biogen has served a rebuttal report responding in detail to and criticizing (Bayer believes meritlessly) Dr. Moore's testing. Biogen simply has not been deprived of relevant discovery.[4]

[4] Biogen's claims that it has been denied an opportunity to take discovery ring especially hollow given that Biogen has not *sought* any further discovery. Any prejudice to Biogen "ha[s] to be viewed in the context of [Biogen's] own failure to take any steps to clarify the facts." *Pennypack*, 559 F.2d at 905. Biogen has not pointed to any information it has been denied or any materials it cannot obtain, aside from a conclusory statement—without saying what information it lacks from other sources—that it could have sought depositions of lab technicians. Mot. at 13.

Second, Biogen claims that Bayer has "frustrated Biogen from conducting its own testing in response." Mot. at 14. Not so. Biogen already has an expert witness capable of conducting a hybridization experiment—Dr. Couceyro *performed* such experiments in connection with his infringement report. And while Biogen describes its difficulty arranging testing with one laboratory capable of working with radioactive DNA labeling, it does not represent that it could not find a suitable lab.

Biogen asserts that Bayer's own testing required more than sixteen months, so that it could not be repeated expeditiously. Mot. at 14. Both assertions are wrong. As explained in the accompanying Declaration of Dr. Gordon P. Moore, the vast majority of the time between the first and last laboratory notebook pages cited by Biogen was dedicated to generating and validating the materials to be tested in the experiment—which Bayer has both described in detail and provided to Biogen. Moore Decl. ¶ 5; Ex. S; Ex. T. The actual experiment required roughly one week. Moore Decl. ¶ 6; Ex. S at 10-27. With the DNA in hand, Biogen's replication of the experiment could thus have been completed in at most a few weeks. Biogen received Dr. Moore's report fourteen months before the scheduled trial date of September 2017, and Bayer consistently offered Biogen flexibility as to the schedule regarding this issue. Biogen had time to conduct its own testing and chose not to do so.

Finally, Biogen argues that the timing of Bayer's disclosures frustrated claim construction. But the hybridization limitation—including the phrases "capable of

hybridizing" and "washing conditions" Biogen identifies—were already construed by agreement. ECF 100-1 at 3. Biogen agreed to a broad construction of this limitation to facilitate its proof of infringement, and the case proceeded under that agreed construction. Now that Biogen is more concerned about the consequences for invalidity, it seeks to narrow the claim. The Court should not permit Biogen to re-draft the claim in hindsight to avoid invalidity.[5] And to the extent a dispute among experts gives rise to a previously undecided issue of claim construction, the Court is free to resolve those disputes in connection with summary judgment or trial. *Conoco, Inc. v. Energy & Envt'l Int'l, L.C.*, 460 F.3d 1349, 1359 (Fed. Cir. 2006).

### C. Bayer Has Acted in Good Faith

As to the final *Pennypack* factor, there is no "showing of willful deception or 'flagrant disregard' of a court order by" Bayer that is needed to exclude this critical evidence. *Seltzer v. I.C. Optics, Ltd.*, 339 F. Supp. 2d 601, 607 (D.N.J. 2004). Bayer served an invalidity contention on Weissmann at the outset of the case and produced the relevant expert materials at the outset of expert discovery. These disclosures were timely, but even if they were not, there is no basis to conclude that Bayer was acting in bad faith or in deliberate violation of the scheduling order.

For all of the above reasons, Biogen's motion should be denied.

[5] Such an effort would be meritless—Biogen's novel suggestion that "washing conditions" requires further construction is belied by the express recitation of the relevant washing conditions in the language of claim 1.

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